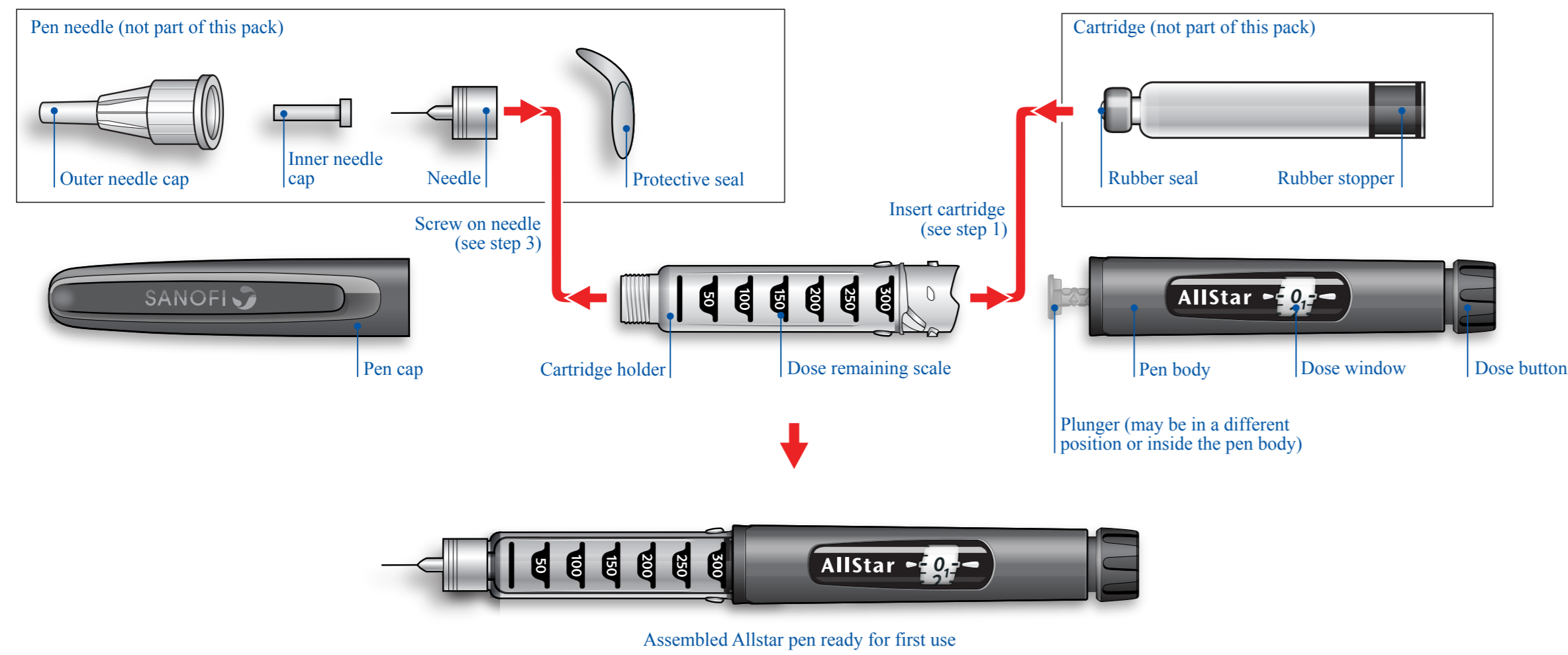


AllStar™ : Read this leaflet carefully

Instruction for use AllStar™ Reusable insulin delivery device



The AllStar components



Assembled AllStar pen ready for first use

Before you start

Read these instructions and follow them completely each time you use AllStar to ensure that you get the right dose.

If you do not follow these instructions completely, you may get too much or too little insulin, which may affect your blood glucose levels.

If you are not able to follow all the instructions completely on your own, are blind or have severe vision problems, use AllStar only if you have help from a person who is able to follow the instructions.

AllStar is a re-usable pen for the injection of insulin.

Talk with your healthcare professional about proper injection technique before using AllStar.

AllStar is a re-usable pen for the injection of insulin.

- You can set doses from 1 to 80 units in steps of 1 unit.
- AllStar can only be used with 3 ml (300 units) insulin cartridges (U-100) from Sanofi Group.
- Each insulin cartridge contains 300 units and can be used for multiple injections until it is empty or 28 days have passed since its first use (whichever comes first).
- The rubber stopper will only move to the end of the cartridge when all 300 units have been given. AllStar has been designed to be used for up to 3 years after first use.

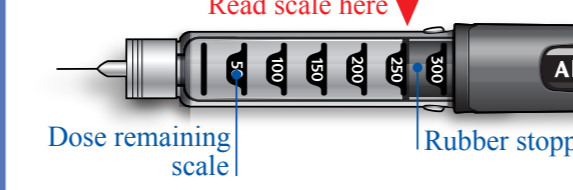
Record the date your pen was first used here:

dd / mm / yyyy

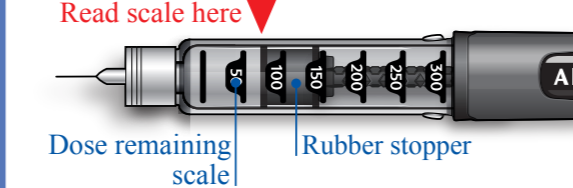
Contact your healthcare professional to get a new AllStar when your pen has been used for 3 years. If you have any questions about AllStar, ask your healthcare professional.

Reading the dose remaining scale

The approximate number of units remaining in the cartridge is shown on the scale by the end of the rubber stopper nearest to the needle.



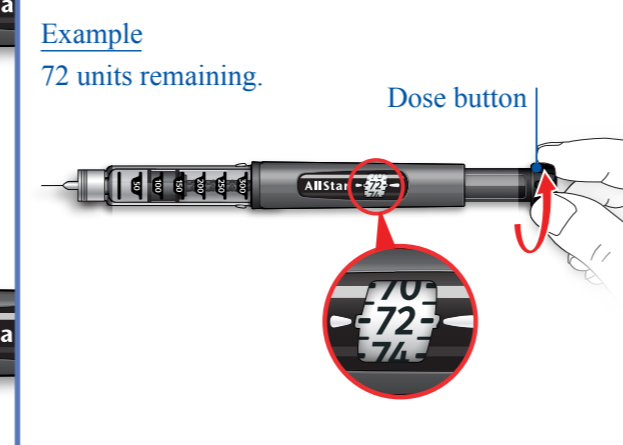
Example 1
Approximately 250 units remaining.



Example 2
Between 50 and 100 units remaining.

You cannot select more units than what is remaining in the cartridge.

- If less than 80 units are left, the exact number can be found by:
 - turning the dose button as far as it will turn easily
 - reading the number in the dose window.



Important information for use of AllStar:

IMPORTANT

- Always check the label on your cartridge for the type of insulin and expiry date before each injection.
- Always attach a new needle before each injection. Use needles from Artisans, Becton Dickinson and Company, Ypsomed and Owen-Mumford. These are the manufacturers that have been approved for use with AllStar. The needle is not part of this pack.
- Always perform the safety test before each injection (see Step 4).
- If you use different types of insulin, you should use a different color AllStar or another Sanofi Group pen for each insulin. You should ensure to differentiate your pens containing different types of insulin.

- If you are giving an injection to another person or if your injection is given by another person, take special care not to touch the needle tip to avoid accidental needle injury and passing infection.
- For use in a multi-patient environment, e.g. hospital or nursing home, special caution must be taken to ensure identification of the correct pen for each patient.
- Each AllStar, each needle and each cartridge are only for one person's use. Do not share with anyone else.
- Never use AllStar if it is damaged or if you are not sure that it is working properly.
- Never use an insulin cartridge if it is damaged.
- Always have a back-up method for delivering your insulin available (e.g. a spare insulin cartridge and a spare AllStar or a U-100 insulin syringe)
- AllStar should not be stored in the refrigerator.

Storage and maintenance of AllStar

Storage Instructions

- Keep AllStar out of the reach and sight of children.
- It is recommended to store AllStar in carry case provided.
- Do not store AllStar in the refrigerator between injections.
- Do not store AllStar with a needle attached.
- If your insulin cartridge is in cool storage (e.g. refrigerator), take it out 1 to 2 hours before you inject to allow it to warm up. Cold insulin is more painful to inject.
- The insulin cartridge can be used for multiple injections – do not remove it from AllStar between injections unless cartridge is empty.
- From when the cartridge is first used, it can be used for up to 28 days under normal carrying or storage conditions.
- Protect AllStar from direct sunlight and from high storage temperatures (e.g. do not store AllStar in a hot car).

See patient insert / leaflet supplied with the 3 ml insulin cartridge for further cartridge storage information.

After the 3 years of using the pen, dispose of the pen safely as instructed by your healthcare provider.

Maintenance

- Protect your AllStar from dust and dirt.
- You can clean the outside of your AllStar by wiping it with a damp cloth.
- Do not soak, wash or lubricate AllStar as this may damage it.
- Your AllStar is designed to work accurately and safely. It should be handled with care.
- Avoid situations where AllStar might be damaged.
- Do not use excessive force when turning or pressing the dose button or when pushing the plunger back in.
- If your AllStar is damaged then it is no longer safe to use.
- If you are not sure whether or not your AllStar is damaged, contact your healthcare professional.

AllStar is a trademark of the Sanofi Group. AllStar meets the current dose accuracy and functional requirements of ISO 11608-1:2000 with Sanofi Group 3 ml (300 units) insulin cartridges (100 units per ml).

Revision date: February 2013

Manufacturer
Sanofi-Aventis Deutschland GmbH
Industriepark Höchst
D-65926 Frankfurt am Main
Germany
www.sanofi.com

Consult instructions for use

Batch code

Keep away from sunlight

Manufacturer



SIL-A-0132113-11 (526885)

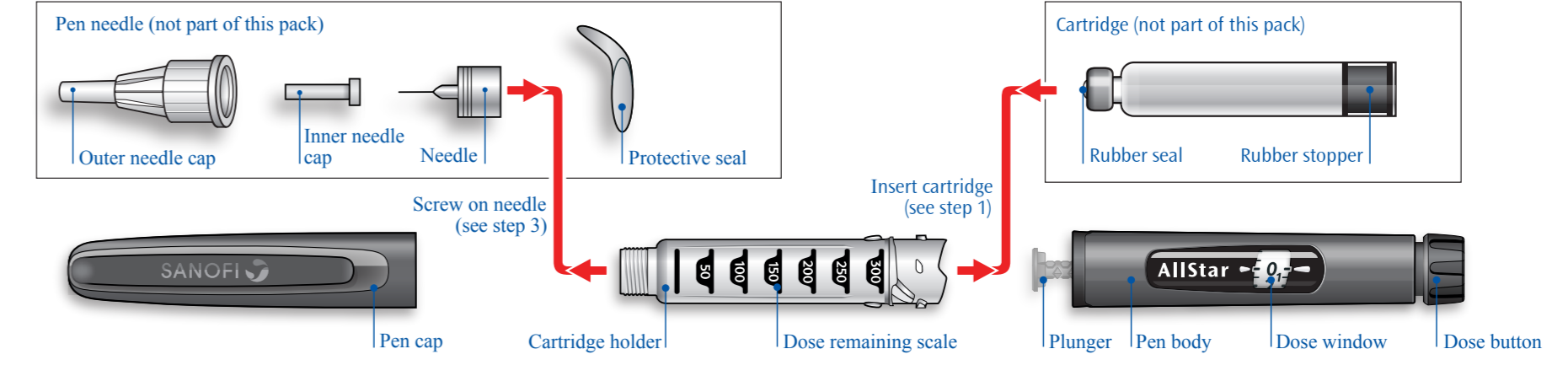
There are important instructions on the other side of the page.

ALLSTAR : GIVING INJECTIONS WITH YOUR REUSABLE INSULIN DELIVERY DEVICE

ENSURE THAT YOU READ THE FULL INSTRUCTIONS FOR USE BEFORE USING ALLSTAR.

What you need for your injection:

- Your AllStar reusable insulin injection pen
- One Sanofi Group 3 ml (300 units) insulin cartridge (100 units per ml) (not part of this pack)



- A new pen needle. Use needles from Artisans, Becton Dickinson and Company, Ypsomed and Owen-Mumford. These are the manufacturers that have been approved for use with AllStar. The needle is not part of this pack.
- A puncture resistant container for disposing of used needles (not part of this pack).

There are important instructions on the other side of the page.

Step 1: Insert a new insulin cartridge

Follow the first time you use AllStar or when replacing an insulin cartridge.

A. Pull off the pen-cap from AllStar.

B. Unscrew the insulin cartridge holder from the pen body.

If there is an insulin cartridge that needs to be replaced, remove it and discard it.

C. Check the label of your insulin cartridge for insulin type and expiry date.

Insert the new cartridge into the cartridge holder.

Do not insert a partially used cartridge.

D. Align the insulin cartridge holder straight with the pen body and use the cartridge's rubber stopper to push the plunger back.

Do not press on the dose button. This will cause the plunger to jam.

E. Screw the cartridge holder firmly back on to the pen body until it clicks into place.

CHECK:

The alignment marks on the cartridge holder and the pen body must line up as shown.

If the features are not aligned, unscrew the cartridge holder and try again.

Step 2. Check your insulin before each injection

A. Check your insulin cartridge label

- Check the label on your cartridge for expiry date and to make sure you have the correct insulin.
- Using the wrong insulin may result in unwanted changes in blood sugar that could be harmful to your health.
- Do not use an insulin cartridge if it is damaged or after the expiry date on the cartridge label.

B. Check the insulin

If you are using clear insulin:

- Do not use the cartridge if the insulin is cloudy, coloured or has particles.

For suspension insulins:

- Turn the pen gently up and down at least 10 times to mix the insulin.
- After mixing, check your insulin. Insulin suspensions must have an even milky-white appearance.

Step 3. Attach a new needle before every injection

IMPORTANT

Always use a new sterile needle for every injection. This helps prevent contamination, inaccurate dosing and needle blocks.

Always attach a new needle before each injection. Use needles from Artisans, Becton Dickinson and Company, Ypsomed and Owen-Mumford. These are the manufacturers that have been approved for use with AllStar.

Please note: The needles shown are only an example – your needles might look different.

A. Remove the protective seal from a new pen needle.

B. Line up the needle with the pen, and keep it straight as you attach it. Screw or push the needle on, depending on your needle type.

C. Take off the outer needle cap. Keep it safe to unscrew the needle after the injection.

Take off the inner needle cap and discard it.

KEEP

DISCARD

CHECK

Make sure that the needle is properly attached.

Step 4. Perform a safety test before every injection

IMPORTANT

Always do a safety test before each injection to make sure that you get the correct dose of insulin.

The safety test removes air bubbles and checks that your pen and needle are working properly.

A. Select a dose of 2 units by turning the dose button.

SAFETY TEST
2 units selected

B. Holding the pen with the needle pointing upwards. Tap the cartridge holder so that any air bubbles rise up towards the needle.

C. Press the dose button all the way in and hold for 10 seconds.

CHECK

- That insulin comes out of the needle tip.
- That the dose window returns to "0".
- If not, repeat the safety test.

You may have to repeat the safety test several times before insulin is seen.

IMPORTANT

If no insulin comes out of the needle tip:

- The needle may be blocked. Remove the needle and replace it with a new needle.
- Check that the cartridge is properly inserted or is not damaged (if it is, use a new one) and is loaded correctly.

After doing all this repeat the safety test again.

If still no insulin comes out do not use this AllStar.

Contact your healthcare professional.

Step 5. Select your dose

The maximum dose is 80 units. If you need a dose greater than 80 units, you should give it as two or more injections.

A. Check that the dose window shows "0" following the safety test.

B. Select your required dose by turning the dose button.

- If you turn past your dose you can turn back in the reverse direction without losing insulin.
- Do not push the dose button while turning, as insulin will come out.

EXAMPLE 10 units selected

EXAMPLE 15 units selected

IMPORTANT

If the dose button does not turn easily do not force it.

- AllStar will not let you select more units than what is left in the cartridge.
- If you need more than what is left you can either:
 - inject what is left, then replace the cartridge with a new one and complete your dose.
 - replace what is left and use a new cartridge for your full dose.

Step 6. Inject your dose

Inject your dose exactly as shown to you by your healthcare professional.

A. Insert the needle into the skin.

B. Inject your dose by pressing the dose button, slowly, all the way in.

C. Keeping the dose button pressed all the way in. Slowly count to 10.

D. Remove the needle from the skin.

CHECK THE DOSE WINDOW

You have received your full dose only if the dose window shows "0".

- If not, repeat Step 6.

Each cartridge can be used for multiple injections up to a total of 300 units.

The rubber stopper reaches the end of the cartridge only when all 300 units have been used.

Step 7. Remove and discard the needle

IMPORTANT

Always remove the needle after every injection. Do not store AllStar with a needle attached.

- This helps to prevent air from entering the cartridge, insulin leakage, contamination, inaccurate dosing and needle blocks.

If you are giving an injection to another person take extra special care not to touch the needle tip.

- This is to reduce the risk of accidental needle injury and passing of infectious diseases.

A. Carefully put the outer needle cap back on the needle.

B. Hold the cartridge holder and outer needle cap.

- Unscrew the needle fully
- Pull off needle

C. Dispose of the needle safely according to local regulation, e.g., in a puncture resistant container.

Step 8. Store AllStar until your next injection

A. Replace the pen cap back on AllStar after use. Store the pen safely until your next injection.

IMPORTANT

You do not need to remove the cartridge after the injection unless it is empty.

- Each insulin cartridge is reusable.
- Your AllStar should be stored with the insulin cartridge inserted, ready for your next injection.

Do not store AllStar in the refrigerator.

Pen and insulin can be safely kept at room temperature up to 25°C to 30°C (77°F to 86°F) depending on the insulin. See patient insert / leaflet supplied with the 3 ml insulin cartridge for further cartridge storage information.

There are important instructions on the other side of the page.

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Global Regulatory Affairs - Atleonor Vigant	1.6	SIL-A-0132113-11	Mr. Vijay Patel
PPAP Packaging team - Sylvia-Marie Brayard	1		12.06.2013
Head ITC - Anilleshwar Mr. G.R. Thiruv	1		
Frankfurt Devices Regulatory Team - Kerin Schenk-Messner	1		
Frankfurt Global Devices Leader Team - Nils Basso	1		
Design Unit	1		

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Packaging material code: 526885
Packaging material name: Leaflet Allstar**
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Reason	Signed by	Date
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Market final validation	Sylvie-Marie Brayard (PPIA Packaging team)	13/06/2013 09:52:27
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